REMARKS

The Office Action dated April 9, 2008, has been reviewed, and the comments of the U.S. Patent Office have been considered. In response thereto, Claims 93 and 94 have been amended, to moot the point the Examiner appears to view as most controversial, the treatment of mammals. The claims as amended require the administration of peptides which interfere with the binding of TSG101 to the Gag complex of HIV infected cells. This is supported, as acknowledged in the outstanding office action, ion the *in vitro* examples of the specification, and the general teaching of the specification, beginning about page 12. Entry is respectfully requested. Upon entry, claims 59 – 91 and 93- 134 remain pending, with claims 59 – 91 and 95 – 131 withdrawn by the pending restriction requirement.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 93, 94 and 132-134 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. This rejection is respectfully traversed. This is the sole basis for rejecting these claims, directed to subject matter acknowledged as novel and unobvious.

The essence of the Examiner's rejection is that it takes far more than *in vitro* trials to demonstrate efficacy of the invention in treating humans and other mammals, *in vivo*. Whether or not this is the proper standard for the Patent Office to apply in determining when a patent application that otherwise comports with the statutes and regulations applicable need not be considered. The question is rendered moot. Upon entry of the amendments set forth above, Applicants claims do not require or even recite efficacy in the treatment of humans. Thus, the

concerns expressed throughout outstanding Action of April 10, 2008 are no longer an impediment to allowance and grant of the presented claims. Thus, at p. 5 of the action, the Examiner observes there is "no evidence that shows any correlation with *in vivo* efficacy." In this regard, the Examiner cites *Ex parte Balzarini*, 21 USPQ2d 1892 (BPAI). Applicants respectfully submit that *Balazrini* is completely distinct fomr the claims presented herein, in that each claims presented the requirement, in the case cited, that the amount given was "effective to treat retroviral diseases in an animal or patient to whom one or more unit doses of said composition are administered." The Board, in affirming the rejection in that case, noted the distinction between claims that require an *in vivo* utility and those which do not.

On page 6 of the application, the examiner cites to four specific difficulties encountered in the art in developing a method for treatment of HIV <u>in humans.</u> Applicants claims do not have this requirement – the methods of the claims have their own utility in providing a means to harness the retrovirus (HIV) replication pathway. Thus, the discussion of clinical trial issues presented at the bottom pf page 6 of the Office Action is noted, but of no relevance to the claims presented. So too are issues involving drug potency, anatomical sanctuaries, selective pressure, etc. discussed on page 7 of the outstanding Office Action.

Applicants demonstrate the invention, giving both specific examples of the peptides contemplated, and an extensive discussion of a routine test to identify other similarly effective peptides based on a measured reduction in HIV particle generation. Moreover, Applicants do not simply offer this phenomenon, but explain the mechanism in detail, disclosing, in Examples 6.1, 6.2 and the consequent discussion that TSG101 protein does in fact bind HIV in the Gag region…that TSG101 binding is essential for HIV particle generation and maturation and

release, and establishing the methods by which effective peptides may interfere with that life cycle, and so, as shown, inhibit particle generation.

While Applicants expressly represent that no in vivo studies are equired, a comment on the Examiner's determination that the in vivo evidence of USSN 11/040,714 is irrelevant (page 9 of the outstanding office action) stands in direct conflict to the examiner's characterization of the claims. The Examiner observes that the evidence in this copending application is in fact directed to the demonstration that TSG101 antibodies interfere with binding to the TSG101 protein when it is on the cell surface, and thus inhibit viral release, in much the same fashion as the peptides of the claims. ***The Examiner has affirmatively represented, unprompted, that such is within the scope of the claims.*** In the office action of August 8, 2007 the Examiner characterized the claims then pending, identical to the claims rejected, as follows:

> The claims read on a genus of unspecified compounds that bind Tsg101 proteins, which encompasses siRNA, apatamers, ribozymes, antibodies, small molecule inhibitors and Gag homologs. Office Action of August 8, 2007, p. 3. (emphasis supplied)

If that is the official position of the Examiner, then the data in USSN 11/040,714 is clearly relevant as within the scope of the claims presented. If the Examiner has decided to reconsider the scope of the claims presented, Applicants appreciate that indication in thenext action, absent a Notice of Allowance.

Given that the claims now reflect a process whose effectiveness is set forth in the specification, a specification which includes in exacting detail how to find other effective peptides by a routine assay that is easily within the skill of those in the art to perform repetitively, the claims are clearly enabled. They require no demonstration of some typeof mammalian or human model effectiveness. And these claims are not otherwise rejected. The sole

rejection for lack of enablement is respectfully submitted to be moot, and withdrawal is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request withdrawal of the single outstanding rejection, reconsideration of this Application and the prompt allowance of at least Claims 93, 94 and 132-134.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 10-0233.

Respectfully submitted,

Date: August 26, 2008
Patent Administrator
Jagtiani + Guttag, LLLP
10363-A Democracy Lane
Fairfax, VA 22030
Telephone: (703) 591-2664
Facsimile: (703) 591-5907
CUSTOMER NO: 22506

/Steven B. Kelber/
Steven B. Kelber
Attorney for Applicant
Reg. No.: 30,073

Customer No. 22506